



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2012-0907; FRL-9379-5]

### **Cyromazine, Silica Silicates (Silica dioxide and Silica gel), Glufosinate Ammonium, Dioctyl Sodium Sulfosuccinate (DSS) and Undecylenic Acid (UDA) Registration Review; Draft Human Health and Ecological Risk Assessments; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration review of cyromazine, silica silicates (silica dioxide and silica gel), glufosinate ammonium, dioctyl sodium sulfosuccinate (DSS) and undecylenic acid (UDA) and opens a public comment period on these documents. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed draft risk assessments for each of the subject chemicals and is making them available for public comment. After reviewing comments received during the public comment period, EPA will issue a revised risk assessment, if appropriate, explain any changes to the draft risk assessment, and respond to comments and may request public input on risk mitigation. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

**DATES:** Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit III., by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** For information about a particular pesticide included in this document, contact the Chemical Review Manager identified in the table in Unit III. for the pesticide of interest.

*For general questions on the registration review program, contact:*  
Jane Scott-Smith, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0048; fax number: (703) 305-8005; email address: [smith.jane-scott@epa.gov](mailto:smith.jane-scott@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager identified in the table in Unit III. for the pesticide of interest.

#### *B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI*. Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:
  - i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
  - ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts and/or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

## **II. Authority**

EPA is conducting its registration review of the pesticides identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

## **III. Registration Reviews**

### *What Action is the Agency Taking?*

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations for cyromazine, silica silicates, glufosinate ammonium, DSS, and UDA to ensure that they continue to satisfy the FIFRA standard for registration—that is, that these pesticides can still be used without unreasonable adverse effects on human health or the environment.

At this stage in the registration review process, consistent with the notice published in the **Federal Register** of August 17, 2012, (77 FR 49792) (FRL-9356-5), jointly developed with the U.S. Department of Agriculture (USDA), the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS) (“the Services”) to enhance opportunities for stakeholder input during pesticide registration reviews and endangered species consultations, draft environmental risk assessments include a screening-level evaluation of the potential risks to Federally endangered and

threatened species (hereafter referred to as “listed species”). EPA intends to complete a refined assessment of potential risks to individual listed species, as needed. The refined listed species assessments will be based on the recommendations of the National Research Council (NRC), which has been tasked with providing advice on ecological risk assessment tools and scientific approaches in developing listed species risk assessments that are compliant with both FIFRA and the Endangered Species Act (ESA). EPA anticipates that the NRC report, expected in spring 2013, will provide recommendations to ensure scientific soundness and maximize the utility of risk assessment refinements for listed species. Additional information can be found at the following website:

<http://www8.nationalacademies.org/cp/projectview.aspx?key=49396>. Useful refinements to the listed species assessments are expected to include, but not be limited to, the following: (1) More detailed, species-specific ecological and biological data; (2) more detailed and accurate information on chemical use patterns; and (3) sub-county level spatial proximity data depicting the co-occurrence of potential effects and listed species and any designated critical habitat.

If, in the event that a draft risk assessment shows risks of concern to human health or the environment for a specific chemical, EPA reserves the right to initiate mitigation at this stage of registration review. This effort to mitigate a chemical’s risks early in the registration review process is consistent with the Agency’s approach for registration review. Where risks are identified early in the registration review process and opportunities for early mitigation exist, the Agency may pursue those opportunities as they arise, rather than waiting for completion of a chemical’s registration review in order to mitigate risks. The public comment period for the draft risk assessments allows members of the public to provide comments and suggestions for revising the draft risk assessments and for reducing risks.

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency’s draft human health and ecological risk assessments for cyromazine, silica silicates, glufosinate ammonium, DSS, and UDA. Such comments and input could address, among other things, the Agency’s risk assessment methodologies and assumptions, as applied in these draft risk assessments.

The Agency will consider all comments received during the public comment period and make changes, as appropriate, to the draft human health and ecological risk assessments. EPA will then issue revised risk assessments, if appropriate, and explain any changes to the draft risk assessments, and respond to comments. In the **Federal Register** notice announcing the availability of the revised risk assessments, if any of the revised risk assessments indicate risks of concern, the Agency may provide a comment period for the public to submit suggestions for mitigating the risks identified in those revised risk assessments. At present, EPA is releasing registration review draft risk assessments for the pesticide cases identified in the following table and further described after the table.

**Table – Registration Review Draft Risk Assessments**

<b>Registration Review Case Name and Number</b>	<b>Pesticide Docket ID Number</b>	<b>Chemical Review Manager, Telephone Number, and E-mail Address</b>
Cyromazine, Case # 7439	EPA-HQ-OPP-2006-	Kelly Ballard

	0108	(703) 305-8126 <i>Ballard.kelly@epa.gov</i>
Dioctyl sodium sulfosuccinate, Case# 4029	EPA-HQ-OPP-2010-1006	Garland Waleko (703) 308-8049 <i>Waleko.garland@epa.gov</i>
Glufosinate Ammonium, Case# 7224	EPA-HQ-OPP-2008-0190	Katie Weyrauch (703) 308-0166 <i>Weyrauch.katie@epa.gov</i>
Silica Silicates, Case# 4081	EPA-HQ-OPP-2007-1140	Laura Parsons (703) 305-5776 <i>Parsons.laura@epa.gov</i>
Undecylenic acid, Case# 4095	EPA-HQ-OPP-2011-0910	Garland Waleko (703) 308-8049 <i>Waleko.garland@epa.gov</i>

### *Cyromazine*

The registration review docket for cyromazine (EPA-HQ-OPP-2006-0108) opened in a notice published in the **Federal Register** of March 28, 2007 (72 FR 14548) (FRL-8118-3). Cyromazine, an insecticide/larvicide, is a member of the triazine class of chemicals registered for use on a variety of agricultural food crop as well as non-food uses such as landscape and greenhouse ornamentals. For cyromazine, the Agency has conducted a human health risk assessment for both dietary (food and drinking water) and occupational exposure pathways. The Agency has also conducted an ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

### *Dioctyl Sodium Sulfosuccinate (DSS)*

The registration review docket for DSS (EPA-HQ-OPP-2010-1006) opened in a notice published in the **Federal Register** of December 22, 2010 (75 FR 80496) (FRL-8857-6).

DSS is registered as an insecticide in pet shampoos and spray products in combination with undecylenic acid. There are no food uses and, thus, no tolerances are established. DSS is also used as an inert ingredient in several end-use pesticide products, disinfectants and sanitizers, and as a wetting agent in industrial, drug, cosmetic, and food products. The Agency has conducted a qualitative assessment of both human health and ecological risks, including listed species for DSS.

#### *Glufosinate Ammonium*

The registration review docket for glufosinate ammonium (EPA-HQ-OPP-2008-0190) opened in a notice published in the **Federal Register** of March 26, 2008 (73 FR 16011) (FRL-8356-4). Glufosinate ammonium is an herbicide that acts by inhibiting glutamine synthetase, which leads to poisoning in plants via the overproduction of ammonia. Glufosinate ammonium is registered for use on a variety of food crops, and is registered for use on non-crop areas such as golf course turf and spot treatments on residential lawns. To support the registration review of glufosinate ammonium, the Agency has conducted a human health risk assessment via a new use risk assessment for citrus, pome, and stone fruits completed July 25, 2012, and an addendum completed on January 24, 2013, that addresses other scenarios not covered in the July 25, 2012 new use assessment. The Agency has also conducted an ecological risk assessment, which includes a screening-level listed species assessment. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

#### *Silica Silicates*

The registration review docket for silica silicates (EPA-HQ-OPP-2007-1140) opened in a notice published in the **Federal Register** of March 26, 2008 (73 FR 16011) (FRL-8356-4). Silica silicates, silicon dioxide and silica gel, are insecticides and acaracides used in controlling insects at indoor and outdoor sites including a variety of crops. Silicon dioxide is diatomaceous earth, a naturally-occurring material composed of the shells of minute, single-celled algae. Silica gel is an amorphous form of silicon dioxide. Because of their abrasive characteristics, both active ingredients affect insects by removing the oily protective film covering their bodies which normally prevents the loss of water, leading to death by desiccation. The qualitative human health risk assessment conducted for the 1991 reregistration eligibility decision (RED) is still considered to be an adequate analysis of potential risks to humans. No new human health toxicology or exposure data were required or are available for silica silicates; therefore, a new human health risk assessment was not necessary to be completed for registration review nor is one being made available for comment at this time. Further, due to low toxicity, and the fact that silica silicates naturally occur in the environment, the Agency has conducted a qualitative ecological risk assessment for non-target terrestrial species. EPA acknowledges that further refinements to the listed species assessment will be completed in future revisions and requests public comment on specific areas that will reduce the uncertainties associated with the characterization of risk to listed species identified in the current assessment.

*Undecylenic Acid (UDA)*

The registration review docket for UDA (EPA-HQ-OPP-2011-0910) opened in a notice published in the **Federal Register** of December 21, 2011 (76 FR 79173) (FRL-9329-7).

UDA is registered as an insecticide in pet shampoos and spray products in combination with dioctyl sodium sulfosuccinate (DSS). There are no food uses and, thus, no tolerances are established. UDA is approved by the U.S. Food and Drug Administration (FDA) as an active ingredient in over the counter anti-fungal products, and it is also used as a flavoring agent. EPA has conducted a qualitative assessment for both human health and ecological risks, including listed species for UDA.

1. *Other related information.* Additional information on cyromazine, silica silicates, glufosinate ammonium, DSS, and UDA is available on the chemical pages for these pesticides in Chemical Search, <http://www.epa.gov/pesticides/chemicalsearch/>, and in each chemical's individual docket listed in Table in Unit III. Information on the Agency's registration review program and its implementing regulation is available at [http://www.epa.gov/oppsrrd1/registration\\_review/](http://www.epa.gov/oppsrrd1/registration_review/).

2. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's

registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.



**List of Subjects**

Environmental protection, Pesticides and pests, cyromazine, silica silicates (silica dioxide and silica gel), glufosinate ammonium (glufosinate), dioctyl sodium sulfosuccinate (DSS), and undecylenic acid (UDA), draft risk assessments.

Dated: February 26, 2013.

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*Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.*

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